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Remarks of
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Subcommittee on Health and the Environment
before
Lifetime Forum
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I'm sorry that I cannot attend this meeting. As you are certainly aware, it is occurring at a time of great difficulty in American foreign policy, and, with the House vote on Contra aid scheduled for this evening, I don't feel that I can afford to leave Washington.

But domestic issues continue, in many ways with increased urgency. This conference is taking place at the beginning of the real budget season, at a time when the groundwork is laid for the rest of the Session's deliberations.

During these budget discussions, it is clear that health programs are under attack as never before. All of us who care about them--as providers, employers, and patients--must work together for their preservation. Without such combined effort from participants in the health care market, few Federal programs will be left intact and effective.

Gramm-Rudman

No where is this more evident than in the enactment of the Gramm-Rudman legislation. As you may know, starting last month, the Medicare program began paying 99 cents on the dollar to physicians, hospitals, and other providers. In addition, most of the health programs within the jurisdiction of my subcommittee were cut by 4.3 percent.

These cuts pose problems in all areas--ranging from research to clinical care. They cause particular difficulties in regulatory agencies such as the FDA and the CDC in which almost all funding goes for staff. Already stretched thin, the staffs are being further reduced in size and we can only expect that work will be slowed, no matter what the de-regulatory rhetoric may be.

As the President refuses to consider reductions in defense or increases in taxes, further Gramm-Rudman cuts--at least twice as deep--can be seen on the horizon for September, and the effect for the patient and the health care industry will be devastating.

I was a conferee on the Gramm-Rudman bill. I did what I could during negotiations to minimize the damage to Medicare, Medicaid and other health programs, but I did not sign the conference report and I voted against passage of the bill.

You may have heard that one of the authors of the bill, Senator Rudman, called it "a bad idea whose time has come." I agree that it is a bad idea, but it is a bad idea whose time should never have come.

President's Budget for 1987

Unfortunately, the President's budget proposals for 1987 are no better. The President proposes to cut federal health spending by nearly $73 billion over the next five years. Medicare would be slashed by almost $53 billion, Medicaid by nearly $10 billion, and biomedical research and public health programs by over $10 billion.

Even the most simple fundamentals are under attack:

The President's budget proposes cutting funds for childhood immunizations against polio and measles, diseases we know we can control.

The budget includes a real decrease of over 20 percent in AIDS activities at NIH and CDC.

The Administration argues that biomedical research be cut by 1,000 new grants and 1,000 new fellowships.

And the President, for the sixth year in a row, is proposing to limit the Federal share of Medicaid and leave States and hospitals with whatever extra costs there may be.

Such proposals are unreasonable. They do not make a coherent approach to the role of government in health care. Those of us who follow the development of public and private health services must speak up to make clear that such actions are unreasonable for the marketplace and unfair for the public.

These budget issues will take up the lion's share of the Congress's health debates for the rest of the year. Physician reimbursement, payment under Medicare for hospital capital expenses, and expansion of community care programs--all will be decided within a general discussion of budgets.

Drug issues

But within this global discussion, there will also be more specific legislative consideration of a number of issues related to the pharmaceutical industry. Let me describe a few of these now.

Drug Export

Probably the most prominent pharmaceutical legislation pending before the Congress is the export from the U.S. of unapproved drugs. Many members of the pharmaceutical industry have proposed to change U.S. law to allow the export of drugs that have not been approved or even reviewed. While I understand and am prepared to consider proposals for some modification of the law, I cannot support such a broad measure.

A bill to permit such unrestrained manufacture and export was reported by Senator Hatch's committee at the end of last year. That bill is very controversial and is still awaiting time on the Senate floor. As many as twenty serious amendments have already been suggested.

In the House, the Health Subcommittee has scheduled hearings this month and next on two different proposals--one that is very similar to the Senate bill and a more limited one that I have drafted.

The main difference between the bills lies in the limitations on exports to countries which do not have relatively sophisticated drug approval systems in place. It is one matter to permit the export of a drug under FDA review to England or Canada: The drug lag involved is a valid economic concern.

But it is a very different matter to permit the export of unreviewed or unapproved drugs to the Phillipines or Brazil or Mexico. In countries without strong consumer protection systems, such export is simply dumping of products unfit for consumers anywhere.

The hearings of my subcommittee this month will be the first comprehensive Congressional investigation of international drug marketing. We will look at the sales of approved drugs overseas and we will look at the marketing of unapproved drugs--especially in less-industrialized nations. And we will investigate those claims

that changes in export law will lead to new jobs or repatriation of foreign facilities. Whatever initial sentiments may be, it is clear that neither the Congress nor the public understands the overseas industry well, and I hope these hearings will clarify the issues.

Vaccine Compensation

We have also begun the process of examining and, I hope, addressing another area of immediate concern--an area that is unique in its policy implications for both public health and tort liability--vaccines.

Childhood immunization have created a public health revolution in this country. Not that many years ago there were thousands of cases of polio and millions of frightened families each summer. Last year there were five cases.

But over the past few years, the price of vaccines for such diseases as polio and whooping cough have skyrocketed, and much of this price increase has been attributed to liability costs.

The problem is simply this: Although almost everyone agrees that vaccination is good for the Nation, vaccines are not completely safe, and some vaccines are more dangerous than others. Children who are completely healthy may be seriously injured or killed by routine immunization.

The response has been an increase in the numbers of lawsuits filed, a reluctance of manufacturers to stay in the market, difficulties in getting liability insurance for manufacturers, and real reservations by many parents about having their children immunized.

This is a problem of unique public health importance:

* Every dollar society puts into vaccine may save as much as 90 dollars in medical costs.

* Since vaccines are not 100 percent effective, it is important for all children to get immunized to protect the society against the recurrence of disease.

And because of these public health concerns over the years, we have already made one unique change in law regarding vaccines: All 50 States require that children be immunized before beginning school.

This is not an assumed risk, this is not true consent. Vaccine injury is a danger we require all families to expose themselves to, for the public good.

Again, the answer to this problem is not simple. Parents with disabled children and manufacturers without insurance both have proposed solutions, as do physicians, public health groups, and the Administration.

After two hearings and an extensive industry survey, I have begun legislative work with my colleagues on the Subcommittee. A lasting resolution must include compensation for injured children and some tort reform. I hope to have legislation introduced for consideration very soon.

Drugs--Generics and prices

Patent-term/ANDA

Another legislative concern for many of you is the area of brand-name versus generic drugs. The recent patent-term and generic drug legislation has already begun to produce dramatic reactions, some good and some bad, and the Congress will be following those carefully this year and for some time to come.

Although most of you are familiar with the law, let me outline what it is intended to do. First, it permits the FDA to approve generic copies of brand-name drugs approved after 1962. Second, it provides major incentives for the development of new drugs by extending patent life and giving some exclusive marketing privileges.

These two changes have already begun to revolutionize parts of the industry. By permitting generic drug makers to copy post-1962 brand-name drugs as soon as patents expire, the Act allows hundreds of drugs to be made available in generic form. These include many of the best-sellers such as valium, motrin, and inderal.

For the first time, there will be price competition on these drugs, and the resulting consumer savings have been conservatively estimated at a billion dollars over the next decade. The 1986 Industrial Outlook of the Commerce Department goes further and says that the generic industry will show an increase in sales of more than a billion dollars in 1986 alone, and that by 1990 about 30 percent of all prescription drugs will be generics.

This is just the beginning of the impact of the law. As insurance companies, hospitals, and public programs become familiar with possible savings, many will begin to shift to generic products.

The legislation also provides for significant incentives for the development of new brand-name drugs. The patent extensions restore much of the time required for a pharmaceutical house to test and license the drug and will extend marketing protections for as long as five years. Co say meant increase R&D —

Problems: Anti-generic campaign

But unfortunately some of the brand-name industry has responded not with re-doubled research efforts, but with an anti-generic campaign. Some pharmaceutical groups are engaged in a multi-million dollar campaign to discourage the use of generic drugs by raising fears and doubts in consumers' minds about the safety and efficacy of generics.

The public and the health care system are the losers in such a campaign. The elderly use thirty percent of the prescription drugs in the U.S. and Medicare does not pay for drugs. Moreover, nationwide data show that 80 percent of the drugs in the U.S. are bought without any insurance, leaving consumers with the full burden of increased costs.

And--adding injury to insult--brand-name pharmaceutical houses are increasing costs of drugs at a phenomenal rate, with no justification other than price gouging. Over the past four or five years, while the CPI has risen a total of about 25 percent, the price of some of the best-selling drugs has risen 65 to 90 percent, sometimes by as much as 25 percent a year.

Such activities do not represent a good-faith response to market pressures. They certainly are not much justification for extensions of patent and marketing rights. And at a time when much of the health care industry is under severe cost constraints, they are a source of great concern to all payors.

Over the next year and on, we will continue to review the anti-generic campaigning and pricing of brand-name drugs.

Drug labeling

During this session, the Congress must take up once more legislation regarding the labeling of prescription drugs. As many of you know, current law prohibits manufacturers from stating that a drug is "FDA-approved." This provision is left over from 1938, when it was adopted to prevent the public from misconstruing approval for endorsement.

The effect, however, is sometimes to leave physicians and pharmacists in the untenable position of not knowing a drug's real status. As you may remember, two years ago over 30 infant deaths were associated with the use of E-Ferol, an unapproved drug marketed as similar to one approved before 1962. And three years ago, a pharmacist gave out an illegally marketed unapproved drug and, when the patient died, was indicted for manslaughter.

Neither case would have occurred had labeling been available. But in both instances, pharmacists and physicians had no way of knowing that the drugs used were unapproved.

The House has passed the bill, but the Senate Committee has yet to take action. I hope that before this Session is over, the Congress might take this simple action to protect providers from liability and patients from unapproved drugs.

Medical devices

Another area of concern for the Health Subcommittee is medical devices. An enormous number of products fall into this category -- from tongue drepessors and bedpans to pacemakers and CAT Scans. Ten years ago, Congress passed a comprehensive bill that, for the first time, gave the Food and Drug Administration the authority, in appropriate cases, to require manufacturers to demonstrate the safety and effectiveness of their devices to FDA before the devices could be marketed. The bill also gave the agency the authority to write safety standards and order recalls of unsafe devices.

Now that the law has been in place for a decade, we have begun reviewing its effectiveness. Although it undoubtedly has provided substantial safety benefits to the American public, we see problems with its implementation.

Two points illustrate the problem. Among other things, the Medical Devices law requires that devices presenting serious safety concerns that were on the market before the law's passage must undergo premarket approval. To date, the FDA has not completed one such premarket approval.

The law also required FDA to establish a category of devices presenting safety concerns serious enough to warrant a safety standard. Not one safety standard has yet been written for any of the over than 1100 devices in this category.

Why no action from FDA? It's not from lack of trying. As I've mentioned before, the agency simply does not have the staff or resources to fulfill its mandate, and Gramm-Rudman will only make things much worse.

Therefore, FDA has had to make some pretty drastic priority decisions. And it has chosen to focus its efforts on new devices coming onto the market for which there is no past experience. FDA's assumption has been that devices already on the market -- for which there is some experience -- probably do not present as much of a risk as those about which we have no information whatsoever.

FDA's assumption may or may not be correct. Let's hope it is. But, even more, let's see if we can't modify the law so that the agency can focus its scarce resources on the most potentially dangerous products.

Animal Drug Legislation

We are also interested in developing legislation regarding animal drugs. The 1984 Generic Drug-Patent Term Restoration Act is a workable model that I expect will be followed in the animal drug field.

Currently, generic copies of off-patent brand name animal drugs have no abbreviated approval mechanism. To be marketed, generic animal drug must repeat the long and costly studies that were required of the brand name drug.

This policy makes no more sense with animal drugs than it did with human drugs. With animal drugs in food-producing animals, there are additional concerns of human food safety. FDA assures me, however, that we can develop an expedited generic approval process that asures that the generic copy is just as safe as the brand name version.

I am currently developing legislation with the advice of the brand and generic drug industries and the FDA that will establish a generic approval system. It also will extend to animal drugs the patent term restoration rules for human drugs.

I believe that the human drug patent extension rules are the appropriate precedent. The Congress considered the need for greater incentives to research and develop sophisticated drug products. The rules for human drugs are the appropriate rules for animal drugs.

AIDS

Let me conclude by discussing a major development that the health care industry has been late to notice: the AIDS epidemic.

The epidemic began in this country in 1981. Since that time, almost 20,000 cases have been reported to the Centers for Disease Control. More cases were reported last year than in all previous years combined and the total is expected to double again next year. It is estimated that at least a million Americans have been exposed to the virus.

This is a serious problem for all of the American health care system. Nationally, the average cost of caring for an patient from diagnosis to death has been estimated to be over $100,000. Ten cases cost the system over a million dollars. Almost forty cases are reported a day.

If the epidemic continues, life and health insurance companies stand to lose hundreds of millions of dollars.

Hospitals stand to lose millions more, since many people have no health insurance now, and, as health insurance companies start to screen out individuals with antibodies, fewer will be able to get it.

Lost productivity has been estimated to have been in the billions already.

As taxpayers, insurance-holders, and employers, you all have a direct financial interest in making certain that the Federal government responds fully to the epidemic--with research, drug development, and education. But the Reagan Administration--penny-wise and pound-foolish and afraid to be seen helping gay men and drug abusers--has consistently short-changed all efforts. We will all have to pay for that neglect.

I ask you, as you go back to discuss patents and drug export and pricing, go back and discuss AIDS with your companies also. Perhaps private initiatives can help in areas that the government ignores. Perhaps you can lend your support to public work. But we can't afford to dismiss the issue.

Conclusion

As you can see, the Congress has a lot of work to do over the next year or two. I'm afraid that the short-term budget issues will dominate all debates. But clearly there will be a great deal of other work as well. I urge you to help us get past the paralyzing budget debates to a time when we can look to the substance of health care.

I look forward to working with you.